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**MARTIN & FERRARO, LLP
1925 Century Park East, 17th Floor
Los Angeles, California 90067**

Telephone
(310) 286-9800

Facsimile
(310) 286-2795

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TO:

FROM:

**Name: Mail Stop AMENDMENT
Art Unit 3738/Examiner Bruce Snow**

Name: Amedeo F. Ferraro

Firm: U.S. Patent & Trademark Office

Phone No.: 310-286-9800

Fax No.: 703-872-9306

No. of Pages (including this): 16

**Subject: U.S. Patent Application No. 09/921,851
Gary K. Michelson, M.D.**

Date: May 4, 2005

Filed: August 3, 2001

Confirmation Copy to Follow: NO

**METHOD FOR FORMING A SPINAL IMPLANT
SURFACE CONFIGURATION**

Attorney Docket No. 101.0084-02000

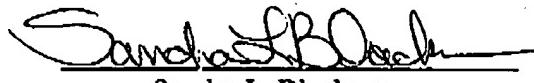
Customer No. 22882

Confirmation No.: 8299

Message:

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that the attached Transmittal Form (in duplicate; \$630.00 total amount to cover the \$450 two-month extension fee and \$180 IDS fee is to be charged to Deposit Account No. 50-1066), Reply to Office Action with attachment, and Information Disclosure Statement with Form PTO-1449 are being facsimile transmitted to the U.S. Patent and Trademark Office on May 4, 2005.


Sandra L. Blackmon

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FORM PTO-1083

Attorney Docket No.: 101.0084-02000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: 09/921,851

Filed: August 3, 2001

For: METHOD FOR FORMING A SPINAL
IMPLANT SURFACE
CONFIGURATION

Confirmation No.: 8299

Group Art Unit: 3738

Examiner: Bruce Snow

Mail Stop AMENDMENT
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a reply to the Office Action dated December 8, 2004 in the above-identified application.

- No additional fee is required.
- Applicant hereby requests a two-month extension of time to respond to the above office action.
- An Information Disclosure Statement with Form PTO-1449 is enclosed.
- The total amount of \$630.00 to cover the \$450 two-month extension fee and \$180 IDS fee is to be charged to Deposit Account No. 50-1066.
- The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. A copy of this sheet is enclosed.
 - Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
 - Any patent application processing fees under 37 C.F.R. § 1.17

05/06/2005 CNGUYEN 00000003 501066 09921851

02 FC:1252 450.00 DA

Date: May 4, 2005

Respectfully submitted,
 MARTIN & FERRARO, LLP

By: 
 Amadeo F. Ferraro
 Registration No. 37,129

1557 Lake O'Pines Street, NE
 Hartville, Ohio 44632
 Telephone: 330-877-0700
 Facsimile: 330-877-2030

05-04-2005 16:36

From:MARTIN&FERRAROLLP

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T-402 P.004/016 F-819

MAY 04 2005

PATENT
Attorney Docket No. 101.0084-02000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Confirmation No.: 8299
Gary K. Michelson, M.D.)	
Serial No.: 09/921,851)	Group Art Unit: 3738
Filed: August 3, 2001)	Examiner: Bruce Snow
For: METHOD FOR FORMING A)	
SPINAL IMPLANT SURFACE)	
CONFIGURATION)	

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TO OFFICE ACTION

In reply to the Office Action dated December 8, 2004, the period for reply having been extended for two (2) months by a request for extension and fee payment filed concurrently herewith, Applicant submits the following remarks.

In the Office Action, the Examiner allowed claims 126-130, 207-220, and 236-257, and indicated that claim 235 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, second paragraph, set forth in the Office Action and to include all of the limitations of the base claim and any intervening claims.

The Examiner provisionally rejected all of the claims under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of co-pending Application No. 10/808,852 (the "852 application"). Applicant submitted a Terminal Disclaimer in the '852 application on May 4, 2005 tying the '852 application to the present application. Applicant submits that the provisional obviousness-type double patenting has been overcome.

The Examiner rejected claims 221-225, 227-234, and 258 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,482,233 to Aebi et al. ("Aebi"). Applicant respectfully traverses the Examiner's rejection.

Claim 221 recites a method for forming an interbody spinal fusion implant, including the step of forming a plurality of surface projections, at least two of the surface

Reply to Office Action 5-4-05.doc

Application No. 09/921,851
Reply to Office Action dated May 4, 2005
Reply to Office Action of December 8, 2004

projections having a forward facet and a rearward facet, "said rearward facet terminating at a first location proximate the base, said rearward facet terminating at a second location proximate said forward facing facet, the first location being closer to the leading end of the implant than the second location."

Aebi teaches an implant 10 having a plurality of spikes 28, the anterior side of each spike being slanted at an angle B which ranges "from about 0 degrees to 30 degrees." (Aebi, col. 4, lines 39-41; Fig. 6). Aebi does not teach or suggest a method for forming an implant as recited in independent claim 221.

Applicant respectfully disagrees with the Examiner's contention that Aebi discloses both the forward facet and the rearward facet having "a negative inclination which produces a portion that extend outside the perimeter of a base portion or 'said rearward facet terminating at a first location proximate the base, said rearward facet terminating at a second location proximate said forward facet, the first location being closer to the leading eng [sic] of the implant than the second location (claim 221)." (See Office Action, paragraph bridging pages 3-4). Applicant further respectfully disagrees with the Examiner's contention that the angles for the steeper angled face disclosed by Aebi as being "from about 0 to about 30 degrees" can "include negative angles." (Office Action, paragraph bridging pages 3-4). Applicant assumes the Examiner is referring to angle B in Fig. 6, described by Aebi at col. 4, lines 39-41. There is no teaching or suggestion in Aebi for angle B to be less than 0 degrees. In Fig. 6 of Aebi, the range of angle B is marked by left and right arrows to either side of the range. The left arrow at the lower end of the range is pointing to the right, indicating that the lower end of the range is at the right of the arrow, i.e., "0 degrees or more." All angles taught by Aebi for the rearward facet are positive.

Applicant respectfully submits that the Examiner used improper hindsight to interpret Aebi to include a method for forming surface projections with rearward facets having negative angles. Every embodiment disclosed by Aebi includes surface projections having rearward facets with positive angles. Nothing is shown or described in Aebi that would lead a person of ordinary skill in the art to believe that Aebi discloses

Application No. 09/921,851
Reply to Office Action dated May 4, 2005
Reply to Office Action of December 8, 2004

surface projections having rearward facets with negative angles. Applicant respectfully submits that the Examiner improperly used Applicant's own disclosure of surface projections having rearward facets with negative angles when interpreting Aebi.

Moreover, when the Examiner reviewed Applicant's disclosure for patentably distinct species, the Examiner determined that rearward facets having negative, positive, and zero (vertical) angles each constituted a patentably distinct species as set forth in the Restriction Requirement dated October 9, 2001 in related Application Serial No. 09/457,228; species 1, Fig. 5, species 2, Fig. 9, and species 3, Fig. 13. A copy of the October 9, 2001 Restriction Requirement is attached hereto for the Examiner's convenience. In particular, the Examiner determined that a configuration of a projection having a vertical rearward facing facet is patentably distinct from a configuration of a projection having a rearward facing facet with a negative direction of inclination. (October 9, 2001 Restriction Requirement; species 1, Fig. 5, and species 3, Fig. 13). Accordingly, Application submits that the step of providing the implant with a rearward facing facet as recited in claim 221 is not obvious in view of a rearward facing facet that is vertical.

Applicant submits that the Examiner's rejection of the claims under 35 U.S.C. § 103(a) in view of Aebi has been overcome.

Applicant submits that independent claim 221 is patentable and that dependent claims 221-225, 227-234, and 258 dependent from independent claim 221, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including

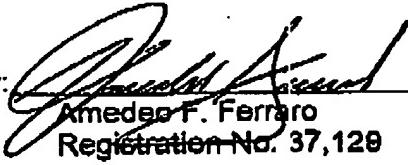
Application No. 09/821,851
Reply to Office Action dated May 4, 2005
Reply to Office Action of December 8, 2004

any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: May 4, 2005

By: 
Amadeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030

05-04-2005 16:37

From: MARTIN&FERRAROLLP

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T-402 P.008/016 F-819



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/457,228	12/08/99	MICHELSON	E 101-0604-000
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022802
 MARTIN & FERRARO
 14500 AVIATION PARKWAY
 SUITE 300
 CHANTILLY VA 20151-1101

QM12/1009

EXAMINER

SNOW, B	ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/09/01

COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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OCT 10 2001

MARTIN & FERRARO LLP

DOCHETED BY: TMM
 ON: 10-PL-1
 ACTION
 REQUIRED: P.L.T

DATE
 REQUIRED: 11-9-01
LIO 11-9-01

Office Action Summary	Application No. 09/457,228	Applicant(s)	COPY
	Examiner Bruce Snow	Art Unit 3738	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire S X (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status 1) <input type="checkbox"/> Responsive to communication(s) filed on _____ 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
Disposition of Claims 4) <input checked="" type="checkbox"/> Claim(s) <u>1-202</u> is/are pending in the application. 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input checked="" type="checkbox"/> Claims <u>1-202</u> are subject to restriction and/or election requirement.			
Application Papers 9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner. 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. § 119 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
Attachment(s) 15) <input type="checkbox"/> Notice of References Cited (PTO-892) 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-848) 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1448) Paper No(s). _____ 20) <input type="checkbox"/> Other: _____			

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Page 2

Application/Control Number: 09/457228

Art Unit: 3738

Response to Arguments

This action is in response to applicant's "Reply to Restriction Requirement", paper No. 7. It was noted by applicant that species 5, indicated as figure 19A, is an enlarged view of Figure 16 and should not be considered a different species to which the Examiner agrees. Species 5 is correctly shown in figure 19B.

Additionally, please clarify figure 17. It is unclear how figure 17 could be a side elevation of the implant shown in figure 16.

Note: the Examiner reserves the right to further restrict this application if deemed necessary or rejection on the grounds of multiplicity as defined in MPEP 2173.05(n).

The previous restriction requirement has been withdrawn, a corrected restriction requirement follows:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-120 and 131-202, drawn to spinal implant, classified in class 623, subclass 17.11.
 - II. Claims 121-130, drawn to a method for forming an interbody spinal implant, classified in class 623, subclass 901.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are

Application/Control Number: 09/457228

COPY

Page 3

Art Unit: 3738

distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process wherein the implant is provided with the surface projections not requiring the secondary step of "forming" the projections.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

species 1 - figure 4

species 2 - figure 8

species 3 - figure 12

species 4 - figure 16

species 5 - figure 19B

species 6 - figure 20

Application/Control Number: 09/457228

Art Unit: 3738

COPY Page 4

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added or the response will be considered non-responsive. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Due to the complexity including multiply species and numerous claims, no call was made.

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Page 5

Application/Control Number: 09/457228

Art Unit: 3738

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Snow whose telephone number is (703) 308-3255.

bes

October 2, 2001

BRUCE SNOW
PRIMARY EXAMINER